

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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THE UNITED STATES OF	*
AMERICA, ET AL. <i>EX REL.</i>	*
JULIE LONG	*
Plaintiffs	*
	*
v.	*
	*
JANSSEN BIOTECH INC.	*
Defendant	*
* * * * *	

BEFORE THE HONORABLE M. PAGE KELLEY
UNITED STATES MAGISTRATE JUDGE
MOTION HEARING
January 13, 2022

Courtroom No. 24
(Via Videoconference)
1 Courthouse Way
Boston, Massachusetts 02210

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P R O C E E D I N G S

(VIA VIDEOCONFERENCE)

THE CLERK: Today is Thursday, January 13, 2022, and we are on the record in Civil Case No. 16-12182, the United States of America versus Janssen Biotech, Inc, the Honorable M. Page Kelley presiding.

Will counsel please identify themselves for the record.

MR. LEOPOLD: Good afternoon, again, your Honor. Ted Leopold, along with my partners, Casey Preston, Gary Azorsky, Diana Martin, and Poorad Razavi.

THE COURT: Okay. Good afternoon to everyone.

MR. POSNER: For the defendant, your Honor, Ethan Posner, Kristen Cobb, Sarah Tremont and Stacey Grigsby, Covington & Burling. Good afternoon.

THE COURT: Good afternoon.

Anyone else?

Okay. So I presume everyone saw that Judge Saylor referred back to me Janssen's objection. And I think what we're going to do right now is -- and he also referred another motion that I think just inadvertently had not been referred to me yet, which I think is 233 on the docket.

So we had said that today I would like to hear argument on 223 and 235, and that's true, and I'm still happy to hear argument on those two motions.

I think these issues are kind of overlapping with some

1 that I've already heard and some things in the objection,
2 but, at any rate, I think I am going to treat the objection
3 as a motion to reconsider. And I've obviously looked at the
4 brief that Janssen filed, which is 252 on the docket, and I
5 think I will just ask you, Mr. Leopold, when are you able to
6 file a response to this?

7 MR. LEOPOLD: Your Honor, thank you. We were in
8 the process of drafting our response to provide to
9 Judge Saylor. I think in terms of the time frame when it
10 was due was -- if I could refer to Casey, I think it's
11 sometime next week. But, Casey, do you have a feel when we
12 can get our response in? Early next week sound fair?

13 MR. PRESTON: I think we're going to need a little
14 bit more time than that.

15 THE COURT: I'm sorry. When was it due, do you
16 know?

17 MR. PRESTON: Your Honor, we were proceeding under
18 the 14-day rule, and I believe the objection was filed on
19 Monday.

20 THE COURT: Right, the 10th. So you want 14 days
21 to respond to that?

22 MR. PRESTON: I guess in light of Judge Saylor's
23 order regarding a clarification, it seemed there was a
24 couple of terms that were used in your December 20 order
25 that Janssen has made issue of in their objection, and we

1 weren't sure if there was going to be a clarification
2 regarding that and then we file our brief, or you want us to
3 file our brief before there's a clarification on those
4 issues?

5 THE COURT: So I think the most streamlined way to
6 proceed here -- I don't want this to get bogged down and for
7 us to have more delay. But I do think the simplest thing is
8 for me to rule on all these motions at once and to do so in
9 more detail than I did in the docket entry from the December
10 hearing. And that way Janssen or relator can take an appeal
11 to Judge Saylor. He can deal with everything at once and
12 not in a piecemeal fashion. And I do think there's some
13 overlapping issues here, and it doesn't really make sense to
14 do them one at a time like this.

15 So I don't want to rush you or have you feel that
16 you're at a disadvantage, but I think if you want to respond
17 to Janssen's arguments that they raise in their brief, 252,
18 that would be helpful, and I will consider it as a motion to
19 reconsider, and I'm reconsidering.

20 So we're not starting from zero, but I am going to take
21 all of these motions into account, deal with all of them. I
22 will issue a written order, and then you can appeal as you
23 wish.

24 So I know you have a status conference with Chief
25 Judge Saylor on the 18th. I don't think I am going to

1 obviously be able to wrap all this up by then, especially if
2 you haven't filed a response by then. So if you wanted to
3 file something on the 24th, which would give you your two
4 weeks, I think that's fine. I am hoping to wrap everything
5 up and get it to you so that you can decide whether and what
6 you want to appeal to Judge Saylor perhaps by the end of
7 that week.

8 So anything to say about that?

9 MR. LEOPOLD: Your Honor, if I may? Could I make a
10 suggestion, that if we could have the time that is allowable
11 under the local rule. We'll do our best to try to get it to
12 you sooner than that if we can, and we'll use our best
13 efforts to do that.

14 And just to clarify, in our, I guess, response to what
15 is now touted as Janssen's motion for reconsideration, we
16 will address all issues that are set forth in there, not
17 only on the issues of clarification or concerns of
18 clarification that they raise, but also responsive arguments
19 of why the court's order should not be reconsidered, or lay
20 out our issues in that regard, I think -- if that makes
21 sense.

22 THE COURT: Yes. And I do think you're welcome to
23 refer to your prior briefing because the briefing was quite
24 extensive and you don't need to repeat it all.

25 MR. LEOPOLD: Right.

1 THE COURT: Okay.

2 MR. LEOPOLD: That makes sense for us as well, your
3 Honor.

4 THE COURT: Okay.

5 MR. PRESTON: Your Honor, if I may? I'm sorry.

6 Just for scheduling purposes, and I know that there's
7 sort of now been kind of a reset on this matter, now
8 switching it from an objection and appeal to a
9 reconsideration. If -- so the 24th -- if we could have
10 until the 26th, I think that that would enable us a couple
11 of more days to be able to provide your Honor with a more
12 robust response to their motion.

13 THE COURT: Okay. That's fine. By the 26th,
14 though, and let's get it in by then.

15 And then my hope is that in February, whichever side
16 wants to take appeals, you can take an appeal, and then I'm
17 hoping things will be settled out for you in February and we
18 can move forward.

19 Okay. So -- and I'm hoping there are no more discovery
20 issues in the pipeline and that this is the universe of it
21 that I have referred to me right now, and I'll take a look
22 at everything and just issue one order on it all.

23 Okay --

24 MR. LEOPOLD: That's helpful. Thank you, your
25 Honor.

1 THE COURT: All right. Now, with regard to 223 and
2 235 -- Mr. Posner, anything else that you wanted to ask
3 before we turn to these two motions?

4 MR. POSNER: No, I don't think so, your Honor.
5 Thank you.

6 THE COURT: Okay. All right.

7 So with regard to 223, this is the oldest of the
8 motions that's pending, and it has to do with relator's
9 request that Janssen be ordered to provide a complete and
10 proper privilege log.

11 And I guess what I really would like to hear from
12 Janssen on this is -- so I do think that relators at the
13 motion for summary judgment stage are going to need to have
14 some -- have had discovery on what we've been referring to
15 as the scienter issue, but whether Janssen knew that what it
16 was doing was unlawful, right?

17 So I just want to make sure that we don't get to
18 summary judgment and there are documents out there that were
19 not -- that you know about but that were not ordered. And
20 I'm noticing the parties just have these diametrically
21 opposed statements. You know, they're saying that you've
22 been ordered to produce evaluations concerning the legality
23 of providing the IOI support, and your response is, We did.

24 So I guess I'm just wanting some reassurance that you
25 actually have provided that information and not just that,

1 Oh, we've never been ordered to provide that.

2 MR. POSNER: Your Honor, my colleagues may address
3 some of these issues. You know, we have certainly produced,
4 you know, detailed policies. There are some more we're
5 going to provide.

6 These are very detailed policies that, in our view,
7 essentially cover the items under challenge.

8 You're not -- just to be clear, you're not ordering us
9 to produce sort of otherwise privileged memos, are you?

10 THE COURT: No. Absolutely not.

11 I guess the problem is, you know, your position is it's
12 too much trouble to go through all the privileged materials
13 because we're just going to produce reams of privilege logs.
14 And I think relator is saying, Well, that's just what we
15 have to do here.

16 And I know earlier in the case I did say I don't think
17 that one of the custodians ought to be a lawyer because it
18 was just going to be a bunch of privileged documents coming
19 from that custodian. And that keeps getting quoted in these
20 papers. But that statement that I made and excluding that
21 custodian really was at a time when I, at least, I don't
22 know about you, but I did not understand we were heading to
23 summary judgment.

24 And so I'm very concerned that we're going to get to
25 summary judgment, information concerning Janssen's

1 scienter -- that's how we're going to refer to it in a
2 shorthand way -- whether they knew that the programs were
3 unlawful, has not been ordered. It's going to become clear
4 during summary judgment that it wasn't ordered, and then
5 we're going to be right back in the same hamster wheel that
6 we're in now going back to look for that stuff.

7 So I do want to make sure that if there is information
8 not in a central repository, which I also don't really
9 understand what a "central repository" is, but if there's
10 information -- if there's categories of information that are
11 not being turned over because you would have to do a
12 privilege log for them, but there are documents among those
13 that are not privileged that are not being turned over,
14 that's troubling.

15 So I just want to make sure we're covering our bases
16 and what I'm ordering you to produce.

17 MR. POSNER: It's not so much what you're
18 necessarily ordering us to produce, although that's part of
19 it, and this is one of the appeal issues, it's more that
20 what your order appeared to require is right -- the time
21 period here is sort of two decades plus. And so you would
22 have had multiple lawyers on these issues. We've obviously
23 produced materials from the Promotional Review Committee on
24 which a lawyer served. But there were multiple lawyers over
25 two decades, as you can imagine.

1 And what your order appeared to require was, Well, go
2 back, find all the electronic documents, go review them,
3 figure out which ones -- which emails and other materials
4 relate to, I don't know, 37, 40 programs over two decades,
5 and go log them all, is what your order required.

6 And obviously that's something that we object to.

7 We obviously have done, you know, a diligent search
8 where we can. But if your question is, Have you gone back
9 over two decades plus, reviewed multiple lawyers' files,
10 present and former, to see what's in there, the answer is
11 we've not done that and we object to doing that.

12 THE COURT: So let me just ask you as a starting
13 point, we're talking only about the programs in this
14 discrete area of Pennsylvania, and is that 37 to 40
15 programs?

16 MR. POSNER: Well, it's at least 37. The relator
17 has answered, and we asked in interrogatory, Okay, tell me
18 what programs you're actually objecting to, okay? And they
19 said, Well, it's at least these 37, but there could be more.

20 So my answer is always, it's at least 37.

21 And, you know, when you look at some other programs
22 they've put under challenge, it's probably closer to 60.

23 And the relator is essentially correct. These programs
24 didn't really vary by district. So they're just challenging
25 the ones in that district, but that's pretty much the

1 national program.

2 So what your order appeared to require, whether you
3 intended to or not, is, Well, go search the lawyers' files
4 going back two decades for, I don't know, 40 to 60 programs,
5 go figure out what's in there, and go log it all.

6 THE COURT: Well, what I'm concerned about is that
7 you have these programs. You're obviously having to comply
8 with a lot of regulations and legal rules about, you know,
9 not violating certain statutes, and I just imagine that
10 there is a body of non-privileged documents discussing their
11 legality.

12 You know, if nothing else, you know, guidance sent down
13 to people in Pennsylvania saying, Make sure if you're doing
14 this, don't do this, and don't cross this line. And, you
15 know, Be careful about this one program because it's right
16 on the line, or that type of thing.

17 Maybe there isn't, but I just think without you
18 searching through every single lawyer's emails for 20 years,
19 you should able to search for and find relevant documents
20 just based on what your client knows.

21 MR. POSNER: Well, your Honor, we have produced
22 very detailed compliance policies. There is not a
23 compliance policy that says, Don't violate the Anti-Kickback
24 Act.

25 There are specific policies on -- that really get at

1 these specific kinds of programs, and there's specific
2 guidance issued to the field which obviously is essentially
3 opining on their legality, right?

4 THE COURT: Right.

5 MR. POSNER: Like it says here's what you can
6 specifically do you in this specific area, reimbursement
7 support, coating support, in-office infusion support.
8 That's what -- I mean, we've given them dozens. We're going
9 to give them some more. But that's what -- that's issued by
10 Healthcare Compliance. Those are compliance policies. And
11 we've given them dozens, and we'll continue to give them
12 more.

13 They just recently sent us an email and said, well,
14 you've given us these couple of dozen. You know, can you go
15 look for these? And we are going to go look for those, and
16 we're going to complete the production on that.

17 That's opining on -- I mean, that's giving compliance
18 to the field.

19 THE COURT: Okay. So that is very reassuring to
20 me.

21 What I am worried about from reading the briefing on
22 this is if it doesn't exist in the custodian's file and it
23 isn't in the central repository, you're not going to look
24 for it. And that's what is troublesome to me, that somehow
25 just -- I mean, what I'm trying to wrap my mind around in

1 this case is there -- obviously once you get out of central
2 Pennsylvania and, as we've been saying, go up the chain to
3 the national oversight of these programs, I can see it does
4 get very unwieldy for you to try to find a needle in a
5 haystack by looking through, you know, many, many employees
6 over many, many years' emails.

7 But what I'm interested in is just institutionally are
8 there other -- maybe that's what you mean by "central
9 repository." But institutionally is there information that
10 relators are not specifically targeting that source but that
11 you know it's there and you're not producing it?

12 MR. POSNER: I mean, not that I'm aware of that
13 otherwise wouldn't be privileged.

14 I mean, I cannot overemphasize the specificity and
15 number of these compliance policies which we've produced and
16 are continuing to produce, okay. That's from -- you know,
17 that resides in the Healthcare Compliance Unit, and that,
18 obviously, we searched, and we tried to find every policy
19 that could conceivably relate to these issues, okay.

20 I'm not aware as I sit here of some other source -- I
21 mean, there could be legal documents flying back and forth
22 over a 20-year period, but if -- I mean, there's no like
23 file -- centralized file that I'm aware of like legal
24 analyses all in one neat place relating to 40 to 60 policies
25 over 20 years. I'm not aware of that. That you would have

1 to go figure out what's in the various lawyer files.

2 But the company has a very sophisticated Healthcare
3 Compliance Unit that issues very specific guidance to the
4 field, including Ms. Long. Whether she got it or not, I
5 don't know, but we're producing that guidance. I mean,
6 that's the guidance to the field on these specific issues.

7 THE COURT: Okay.

8 So let me hear from your team, Mr. Leopold.

9 MR. LEOPOLD: Thank you, your Honor.

10 Your Honor, I think you have focused myopically on the
11 exact core issue, and I think we've heard for the first time
12 after all these hearings that, in fact, Janssen has not
13 looked for the types of documents that we have requested and
14 that your Honor has ordered.

15 I think also -- and I'm not sure if your Honor -- if
16 the transcript has been released or if you have read it from
17 the last hearing with Judge Saylor, which occurred on, I
18 believe, December 22. Because it was on December 21 wherein
19 Judge Saylor asked and had ordered, or maybe you had ordered
20 and he knew about the order, that Janssen had to set forth
21 its position about the reliance of counsel.

22 THE COURT: I did read that, yes.

23 MR. LEOPOLD: And at that time, with all due
24 respect, the letter setting forth their position, I don't
25 want to say it was vague, but a little bit open-ended, that,

1 at least for now, they're not relying on advice of counsel
2 but they may in the future. And Judge Saylor was candidly
3 quite dogmatic saying, Don't think you're going to come back
4 in five, six months or nine months and change your position.
5 And he wants this issue teed up immediately, and we are in
6 the process of drafting an appropriate motion specifically
7 related to that issue that he asked us to do.

8 THE COURT: So can I just ask --

9 MR. LEOPOLD: Yes.

10 THE COURT: -- what's that motion?

11 MR. LEOPOLD: That motion is to set -- to request
12 that Janssen identify or set forth with specificity now, or
13 when this motion is filed, their position on whether or not
14 they are going to rely on the advice of counsel defense.

15 Because in their letter that they provided, again it
16 was quite open-ended, where they -- I don't have it in front
17 of me, but it was something to the effect, right now we
18 don't anticipate doing that, but it may change down the
19 road.

20 And Judge Saylor on his own said, Don't think that
21 you're going to come back six months from now and change
22 your mind or nine months from now that you're going to do
23 that. That's not going to happen.

24 So he -- when -- in that discussion section, he wanted
25 this issue teed up essentially in finality.

1 And so we're making a motion. We're in the midst of
2 drafting a motion on that particular issue.

3 But the second thing that also transpired at that
4 hearing is Janssen argued that although they're not relying
5 on the advice of counsel, this went through a process of the
6 PRC, and there's a lawyer sitting on the PRC that was
7 involved in those decisions.

8 But we don't know all the lawyers. We have no clue.
9 And they have refused to provide anybody at this point,
10 providing testimony, and I'm assuming they're going to
11 object at this point based upon their position.

12 What analysis did they do? Was it just looking at the
13 PowerPoint? Was it making some comma changes? Was it
14 making word changes? Was there an actual legal analysis?

15 But it's a little bit, as we know and we've talked
16 about, and the case law is quite clear on this, a sword and
17 a shield.

18 They're saying, We had lawyers on the PRC that reviewed
19 it, but you don't get to ask them what their review was,
20 what their analysis was.

21 That's number one.

22 And number two, as we heard now affirmatively for the
23 first time, they never went -- have checked at their legal
24 office counsel who else did any review if anyone.

25 And I keep hearing about sort of this 20 years, 20

1 years, 20 years. Like this is a huge burden. I mean, I
2 realize 20 years is a lot, but the program, it's not our
3 fault, started 20 years ago. It is still continuing today.
4 I've never heard of a party saying because it's 20 years
5 long and we've been doing it and we're still doing it, we do
6 not have an obligation to go back and search. We do not
7 have an obligation to provide a privilege log. We do not
8 have an obligation to set everything forth in a privilege
9 log.

10 The rules -- I am not aware anywhere in the rules that
11 says you don't have to do that. I mean, that is just
12 totally contrary to the Rules of Civil Procedure.

13 So here they say, There's somebody on the PRC. There's
14 a legal person. We have no clue what that person does other
15 than, from what we can see in the PRC documents, looking at
16 commas and maybe some word changes because there's no
17 analysis. There's nothing indicating what that lawyer has
18 done, and they're objecting to producing any information
19 about what that lawyer and the PRC has done.

20 They're -- right now we had depositions set. They're
21 refusing to produce anybody for deposition until all of
22 these issues get resolved because they say they don't want
23 to produce anybody twice. So we're now off the calendar for
24 any depositions for weeks, if not months, at this point.
25 That was unilaterally done by the defendants, and at this

1 point there's nothing new that is -- that -- that -- that is
2 -- isn't required.

3 The third issue that I think is very important, it's
4 great to have policies and directives, and even though
5 discovery, we have been told, was completed in October, we
6 are still getting documents. We still have to tell them
7 they still need to find documents. But policies in and of
8 themselves mean nothing.

9 It's great to have a policy, but what is the analysis
10 behind whether or not these policies were followed? So you
11 have programs. The policies say, X, Y, and Z, you can't do
12 this, that, or the other. That's the policy.

13 What was the rationale analysis of the particular
14 PowerPoint of the 27 or so that we gave them?

15 And we're not talking 60. We told them, these are the
16 27 or 30, whatever number we've given them, are the ones at
17 issue. We're not going above that. We've told them this a
18 number of times.

19 So these are the 20- or 30-so programs. Where is the
20 analysis of whether or not they complied with the policies?
21 It's great to have the policies. We expect and suspect that
22 because these programs violate those policies -- from the
23 ones we've seen it's clear they do -- where's the legal
24 analysis?

25 Maybe they didn't do it. That's fine. Then the answer

1 is "none." But we're entitled to know where those documents
2 lie and with whom.

3 And additionally, you know, these people were not in
4 outer space where they don't know who they were. Clearly
5 over the last 20 years they haven't had that much turnover.
6 They know who was involved in reviewing these programs at
7 the general counsel's office. It's not like they have to go
8 search a thousand people. There's somebody there that
9 knows, and they should have to go and... (inaudible) them.

10 THE COURT: First of all, I'm looking at your brief
11 on page 6, and you say -- what you're actually requesting
12 are, No. 1, The various internal assessments, evaluations,
13 and analyses set forth in certain requests, corporate
14 integrity agreements to which Janssen has been a party,
15 documents concerning governmental investigations, documents
16 concerning complaints submitted to the legal or compliance
17 department.

18 So are these actually the detailed things you're
19 seeking, or is what you were just talking about something
20 else?

21 MR. LEOPOLD: First, your Honor, if I could just
22 inquire, your Honor? Are you --

23 THE COURT: I'm looking now at 235.

24 Because I don't know how realistic it is that Janssen
25 is going to go through every lawyers' communications about

1 this and create a privilege log for every lawyer over a
2 period of time like that. I mean, I just wonder if there is
3 a more targeted way of requesting this.

4 I am trying to think, What isn't privileged that you're
5 asking for? What would not be privileged?

6 I know -- okay, here's a business. They're doing
7 something where they have to be very conscious of complying
8 with the law. They must be evaluating whether they are
9 complying with the law or not. But I do think they have an
10 argument that over a long period of time like this for them
11 to just search through all their lawyers' emails, et.
12 cetera, is too much.

13 So what is it you want them to do?

14 And, you know, I'm looking at this list of things which
15 look like they're probably not privileged in the companion
16 motion that we're looking at, just in your request for
17 production.

18 MR. LEOPOLD: Well, I think Casey wants to --
19 because he's been dealing with this particular issue.

20 Casey, do you want to address that?

21 THE COURT: Mr. Preston, yes.

22 MR. PRESTON: Yes.

23 Good afternoon, your Honor.

24 So you're referring to the new requests in the third
25 set. And, you know, those we sort of take a more targeted

1 approach, as the Court instructed, regarding scienter issues
2 and other issues that came up that we've learned of to this
3 point in the case.

4 And, your Honor, in many cases those documents won't be
5 privileged. And they should go and retrieve those documents
6 from employees who were involved in this program and who
7 have knowledge and, you know, are known to have discoverable
8 information.

9 But I think, going back to your concern about the
10 actual privilege log, I think it's important to understand
11 that you have the Promotional Review Committee that did have
12 a lawyer involved. And that lawyer, according to their
13 policies, would have looked at the legality of these
14 programs under state law and federal law. And they're now
15 using that really as a legal opinion, as Mr. Posner has
16 indicated.

17 But at the same point, you know -- so they've injected
18 into this case their knowledge of the law, and they want to
19 use --

20 THE COURT: Can I ask you a question?

21 With regard to the PRC materials where there is a
22 lawyer sitting on the committee, as you would expect there
23 to be, are they claiming those materials are privileged?

24 MR. PRESTON: Your Honor, they have given us the --
25 basically the legal conclusion, approving, rubber stamping,

1 that particular promotional piece as approved. But what
2 they haven't shared is any legal analysis that might have
3 occurred behind the scenes.

4 And so again they're using this as a sword and a
5 shield, and while they're claiming, No, we're not relying on
6 advice of counsel, in fact, that's exactly what they're
7 doing because they're saying, This is a legal opinion that
8 what we were doing complied with the law, and they're
9 relying upon that.

10 And at the same point, they're shielding us from the
11 other legal opinions from their legal department related to
12 this overall IOI support program and individual
13 presentations.

14 And that's why actually it's extremely important here
15 not just for summary judgment but for this whole issue of
16 what actual legal opinions exist and what they're trying to
17 shield, because we are going to -- in our view, they've
18 actually waived their right to withhold those opinions
19 because they have injected into this case their knowledge of
20 the law, right. They have asserted a defense that they've
21 acted in a good-faith belief that they were providing these
22 programs lawfully. And they're relying upon the legal
23 opinion of the Promotional Review Committee.

24 At the same time, they want to shield other legal
25 opinions, which clearly puts us at a disadvantage, right.

1 The defendant can't selectively choose which legal
2 opinions the court and the jury gets to see, when they're
3 going to disclose some legal opinions, and at that point
4 they really have to be compelled to disclose all the legal
5 opinions.

6 MR. LEOPOLD: Your Honor, if I could just take that
7 one step further, just so we can see how it plays in a trial
8 or summary judgment, primarily in a trial, is what they're
9 doing is, Here's the PRC. It's rubber stamped that it's
10 approved. Hey, there's a lawyer on it, so it's okay. But
11 you don't get to see the legal analysis that was done, if
12 any. You just have to take our word for it.

13 Well, you can't have it both ways. You can't have it
14 again. You can't have your cake and eat it too.

15 They put this up front as a main issue. They're
16 saying, The PRC, there's a lawyer on it. It's good to go.
17 We signed off on it. But you don't get to see what the
18 analysis was.

19 We can't even ask questions about it. That's their
20 position. It's all privileged. But the PRC reviewed it and
21 approved it.

22 THE COURT: Just with regard to the PRC argument
23 here, Mr. Posner, you want to respond?

24 MR. POSNER: Well, we're getting really far afield.
25 If they have some brief they want to file about, Because

1 we're claiming the programs were lawful we've waived, they
2 should cite some cases for that proposition.

3 THE COURT: I agree. I think this hasn't really
4 been briefed. But I do still think -- I mean, again, I was
5 hoping we could deal with everything.

6 MR. POSNER: Right.

7 THE COURT: And this isn't going to keep going on
8 and on.

9 But, you know, the question of whether you've produced
10 an adequate privilege log for the materials that you've
11 already done the log for, I think is different than, Have
12 you searched far and wide enough for privileged documents,
13 you know, looking through your privileged documents to see
14 are there things in there that are not privileged that
15 should be turned over? And now this PRC issue I think is
16 another whole can of worms.

17 MR. POSNER: Well, look, we've certainly searched
18 in a bunch of different -- I'm trying to distinguish between
19 doing a good-faith search in a reasonable number of places
20 and then logging those materials, which we've done. We've
21 logged materials that go back at least to 2003 and maybe
22 earlier, okay.

23 Where I was having a problem was the idea that we had
24 to do more than that, that we had to go back and, you know,
25 search multiple lawyer files over a long period of time.

1 The rules require a good-faith reasonable search that's
2 proportionate to the case, and obviously we think we've done
3 that.

4 So -- I'm sorry. What was your question?

5 THE COURT: So I guess the problem is, you know,
6 you're saying, We have done a good-faith reasonable search
7 proportionate to the case, and relator's position is, No,
8 you haven't.

9 MR. POSNER: Yes.

10 Relator's position is -- right. You've got to go back
11 and look at all the lawyer electronic documents, to the
12 extent they exist, and you've got to log everything. That's
13 their position.

14 MR. PRESTON: Your Honor, there's also -- what
15 Mr. Posner is saying just isn't true because, your Honor, in
16 their -- they've disclosed one lawyer. We know there's been
17 several lawyers who have been involved in reviewing the
18 programs and IOS support, but they've identified one, and
19 that is Mr. Jimenez. And they didn't log any of
20 Mr. Jimenez's documents on their privilege log.

21 They're acting like they are completely excused from
22 having to log legal opinions, and legal opinions are really
23 at the center of this case.

24 And so the current privilege log, that only includes
25 documents from the ESI searches that they performed of the

1 12 custodians, none of whom are in the legal department, and
2 some documents that they obtained from their corporate
3 repositories.

4 But as far as any legal analyses and legal opinions
5 from their legal department, they have completely ignored
6 that. So we have no idea --

7 THE COURT: So other than your argument about the
8 sword and shield and that they ought to -- and that they've
9 waived a privilege, why do you think their internal
10 assessments, evaluations, and analyses would not be
11 privileged? Under what circumstances do you have those kind
12 of things that are not privileged?

13 MR. PRESTON: Because they're not just denying our
14 claim that they knowingly provided these services in
15 violation of the law. They are asserting an affirmative
16 defense voluntarily where they are saying they had a
17 good-faith belief that they acted in compliance with the
18 law.

19 And the law is clear. When you voluntarily inject your
20 knowledge of the law, and then you add to that legal
21 opinions, like they are using these Promotional Review
22 Committees, then they have made an implied or an at issue
23 waiver.

24 THE COURT: So is this the motion that you still
25 have yet to brief?

1 MR. PRESTON: We are preparing that motion, your
2 Honor.

3 But I think going back to the privilege log issue, it's
4 essential that we have a privilege log so we know what other
5 legal opinions out there are they trying to shield at the
6 same time they're trying to assert, Oh, well, our policies
7 covered this, and the Promotional Review Committee were
8 relying on those legal opinions.

9 We're entitled to know what other legal opinions exist.

10 MR. LEOPOLD: And, your Honor, on the privilege log
11 that has been provided, specifically related to the PRC,
12 there's no legal analysis review of documents that are set
13 forth on the privilege log from the PRC.

14 It's just -- the documents they have given us just has
15 who the lawyer is and the signature block, and okay, and
16 stamped good to go. There's no other -- there's nothing on
17 the privilege log saying, and, in addition, the lawyers did
18 X, Y, Z in terms of analysis or whatever the privilege may
19 be in setting forth appropriate detail as required by the
20 federal rule. There's nothing on there.

21 So where's the information that should go on the
22 privilege log if what they say is true, that the lawyer and
23 the PRC did an analysis and they were told it's okay? Why
24 isn't that on the privilege log?

25 Along with the other aspect that Casey was just

1 referencing, what legal counsel's office did in addition to
2 the lawyer, the particular lawyer, on the PRC did.

3 MR. POSNER: Your Honor, our log has materials from
4 outside counsel. It has items from in-house lawyers.

5 I don't know where this is going.

6 MR. PRESTON: That's just not accurate.

7 THE COURT: Can I just ask you, how long is
8 privilege log?

9 MR. POSNER: That I'm going to have to defer on.

10 MR. PRESTON: Fourteen pages, your Honor.

11 THE COURT: Excuse me?

12 MR. PRESTON: Fourteen pages, your Honor.

13 THE COURT: Okay. That seems very manageable.

14 So why don't you submit -- I mean, there's a lot of
15 back and forth here about just the adequacy of the log, not
16 necessarily all the documents that have been reviewed.

17 But just with regard to the log as it presents itself
18 being adequate, why don't you just submit the log to me
19 under seal, and I'll take a look at the log, especially if
20 it's only 14 pages.

21 MR. PRESTON: Your Honor, we have done that. I
22 think you have a copy of the log.

23 THE COURT: Oh, I do? Okay.

24 So let me just say, when do you anticipate filing this
25 additional motion, Mr. Leopold?

1 MR. LEOPOLD: Your Honor, we hope to do that within
2 the next two weeks. We are drafting it.

3 And I'm assuming Janssen is aware of this. There is a
4 number of Circuit Court decisions, out of the Eleventh
5 Circuit, out of your Circuit and others, that support our
6 position that you can't have a sword and a shield, and you
7 can't make these statements and then not open it up. But
8 that's a different issue for down the road. I get that.

9 All we're seeking now is, A, confirmation that all of
10 the analyses of lawyers on the PRC are set forth in the
11 privilege log. I don't think that that's been done.

12 Secondly, all other analyses by general counsel's
13 office related to these 27, or approximately 27, programs is
14 on a privilege log. They have not done that. Mr. Posner
15 has stated they have not done that today.

16 We are entitled to get that, because at some point in
17 time, and we think we're on very good ground based upon the
18 circuit court opinions around the country, including your
19 circuit, that those documents are going to become available
20 and will need to be produced based upon the position of
21 Janssen in this matter.

22 MR. POSNER: Your Honor, obviously that -- if
23 they're talking about some sort of waiver argument, they can
24 make that argument.

25 Our point is that we have done a -- we haven't just

1 logged things that were from the custodians. We've logged a
2 number of items, you know, from outside counsel, from a
3 number of other sources, that we were reasonably able to
4 find. So where the debate has been is how -- you know, what
5 other lawyers do we -- I mean, we've obviously produced a
6 lot of PRC records. They can see the names of the lawyers
7 who participated in the PRC.

8 But what we have objected to is the idea that we have
9 to search, you know, through the electronic and other
10 documents of lawyers going back as far as the Court's order
11 appeared to require.

12 THE COURT: Okay.

13 MR. PRESTON: Your Honor, just one other point.

14 Janssen has gone through great effort. They're now
15 going to an outside warehouse to gather all these PRC
16 materials that they want to use as a sword, right. But what
17 they want to be excused from is just logging all the legal
18 opinions that they want to shield that may undermine their
19 claim that they acted lawfully or knowing -- they had a
20 good-faith belief that they acted lawfully.

21 So they're engaging in the effort to collect documents
22 that they want to use, but they're engaging in no effort to
23 collect documents that actually may undermine their
24 position.

25 MR. POSNER: Obviously that's not the case.

1 MR. LEOPOLD: I would like to see -- respectfully,
2 we're talking about the law, and Janssen keeps arguing they
3 haven't seen the law on the sword and the shield and waiver.

4 I would like to see the law where it says they don't
5 have to go and search and put items on a privilege log that
6 relate specifically to the issues in the case. I haven't
7 seen any case law, other than them arguing, well it's just
8 too burdensome for us to do it. Where is an affidavit
9 saying that? I just never heard of that argument before.
10 And I've been involved in cases where products or issues go
11 back longer than 20 years. I've never heard this argument
12 before.

13 You know, we are entitled to a privilege log,
14 especially when it goes to the core issue in the case that
15 they're relying upon, that everything was reviewed, the
16 lawyers signed off, but, guess what, guys, you don't get to
17 see what they are.

18 That's fine. Then put it on a privilege log, and when
19 we show them the circuit court opinions from around the
20 country saying they can't do that, then we'll be asking for
21 all those promotional documents to be produced. They're
22 going to have to produce them at some point, we believe. At
23 least at a minimum they have to put it on a privilege log.

24 I have just not heard of an argument that, you know,
25 just because we have to go back and ask some people about

1 documents going back 10, 15 years on 27 programs, we don't
2 have to do it.

3 It's just -- respectfully it's just -- you know, it's
4 just they don't want to do it because they know what's
5 there, candidly.

6 THE COURT: Okay.

7 I will ask you, if you're going to file something about
8 waiver or, more particularly, that the PRC materials are
9 used as a sword and a shield, et cetera, then I'll ask you
10 to do that within around the next two weeks approximately.
11 I won't hold you to 14 days or anything, but I would like
12 that to get teed up.

13 MR. LEOPOLD: We already have a draft circulating,
14 so it should not be a problem.

15 THE COURT: Okay.

16 Let's look at 235, which is asking for a lot of
17 particular things, and I think what I was already talking
18 about on page 6 are things that you're requesting.

19 And I think, Mr. Posner, I don't know if someone on
20 your team wants to address these requests.

21 First of all, I do think things have changed over time
22 since the discovery here began. And I know that this is a
23 third set of requests for production and you have a section
24 objecting to that. But I am inclined to look at this and to
25 see if any of this should be produced because I do think in

1 my understanding the summary judgment motion was not really
2 clear, you know, that that's where we were headed months and
3 months ago.

4 So, anyway, does someone want to talk about the
5 request?

6 MS. COBB: Sure, your Honor, I can handle that.

7 So, I mean, you've read our motions and you understand
8 that we think that scienter has always been an issue, and
9 these requests have come really late in discovery and that
10 they're not appropriate at this time.

11 But in terms of these specific requests, we do think
12 that most of them are duplicative or cumulative of topics
13 that were included in relator's previous RFPs, to which we
14 have already responded.

15 Relator specifically says that these are more detailed
16 and targeted than the prior requests, but that's sort of the
17 exact definition of a duplicative and cumulative request.
18 This supposedly more-detailed request would be subsumed
19 within relator's previous broad requests.

20 With specifically the requests on the top of page 6. I
21 mean, we don't -- we think that they are unrelated to the
22 programs and services at issue here.

23 The corporate integrity agreements for other cases we
24 just don't think is relevant to what's at issue here.

25 Some of their other requests, including RFP 47 and 58,

1 they're requesting things like documents concerning services
2 similar to ones at issue here. Those are outside the scope
3 of the claims here as well as this phase of discovery. So
4 we think they're beyond what Rule 26 permits.

5 THE COURT: So let me just ask relators, what about
6 that, because it does seem pretty broad?

7 MR. PRESTON: Your Honor, I think that -- again the
8 key issue in the case, or one of the central issues in the
9 case, is Janssen's knowledge of the law, right, whether they
10 knew that providing those services was unlawful.

11 And we know that they were under a corporate integrity
12 agreement related to fraudulent conduct related to other
13 products during the relevant time period. And, you know,
14 that goes to their knowledge of the Anti-Kickback Statute
15 and what types of conduct violates the Anti-Kickback Statute
16 and what type of conduct violates the False Claims Act. So
17 that's why we want to know when they were subject to
18 corporate integrity agreements.

19 With regard to --

20 THE COURT: So -- excuse me.

21 So you want all corporate integrity agreements during
22 this time period related to anything, not necessarily these
23 services? Anything in the whole company?

24 MR. PRESTON: Well, with regard to the defendant,
25 Janssen Biotech, and we're aware of -- it's public

1 information that they were subject to a corporate integrity
2 agreement. That may be the only one. But there may be
3 additional corporate integrity agreements that we're not
4 aware of. But that's the information we're seeking.

5 MR. POSNER: Your Honor, just quickly.

6 Corporate integrity agreements are available on the OIG
7 website. They can just get it from there. Obviously, just
8 to be clear, none of the corporate integrity agreements
9 related in any way to this case, but if they want to
10 download corporate integrity agreements, they can do that on
11 the OIG website.

12 MR. LEOPOLD: Your Honor, I think -- (inaudible) --
13 emphasize what these issues are.

14 There are three categories of documents in this
15 particular docket request, which is Janssen's knowledge
16 concerning the value of these programs, their intent, and
17 whether or not they knew that providing these free support
18 services was unlawful.

19 We have, at the Court's request, been very narrow and
20 focused with these requests for these documents.

21 If the response is, We have produced to you all
22 responsive documents, that's all they need to say. They
23 don't need to go back and regurgitate or reproduce
24 documents.

25 What I don't want to have happen, which has happened

1 before, is when we're sitting in the courtroom at trial, all
2 of a sudden they say, Well, there are other documents, or,
3 Here are new documents that we didn't provide because we
4 weren't specific.

5 All they have to do, if they've produced everything
6 that they say that they have that are responsive to these
7 particular issues is to say that. But it's not a game of
8 "gotcha." So let us know, and if there's anything
9 privileged, provide it.

10 The other thing that they also have said in response to
11 No. 40 and No. 48 is we know that they are in communication
12 with the Department of Justice because they are seeking
13 documents from the government, and there are back-and-forth
14 negotiations with the government and objections by the
15 government. And they're saying, We're not going to produce
16 you documents for 40 and 48 until we work through all of the
17 objections with the government and we get that all squared
18 away.

19 Well, that's another new area of law that I've never
20 heard of either.

21 We haven't gotten any documents or letters indicating
22 what those objections are. We haven't received anything
23 what their negotiations are. I don't know if they're
24 planning to file a motion to compel, but we shouldn't have
25 to wait months and months while they're negotiating with the

1 government about what to get. And, in the interim, their
2 position is, We're not going to produce anything to you
3 until all those issues with the government are resolved.

4 That's not right.

5 THE COURT: So Request for Production No. 40 reads,
6 "All documents concerning the assessment, evaluation, or
7 analysis of any guidance or advisory opinion from the OIG
8 related to the types of services that may implicate the AKS,
9 including, but not limited to, product support services."

10 MR. LEOPOLD: Right. And the reason for that
11 request is that because on numerous occasions Janssen has
12 argued before your Honor and before Judge Saylor, Oh, well
13 we asked the government if -- and OIG if these are
14 appropriate, et cetera.

15 And they said they've had all these communications. We
16 can't find anything. The government can't find anything.
17 But yet their position is, We've communicated with them.
18 We've asked them for that.

19 And so we need something in writing from Janssen
20 indicating what those are. Produce us those documents.

21 And now they're of the position they're trying to get
22 that evidently or allegedly from the government, that I'm
23 not aware exists, according to the government, but Janssen
24 says it does. So produce the documents to us.

25 THE COURT: Okay.

1 And what does Janssen say to this?

2 MR. POSNER: I'm sorry. Kristen, why don't you
3 respond.

4 MS. COBB: Yes.

5 MR. POSNER: None of what -- if the question is did
6 we get some like explicit go ahead from OIG at the time,
7 we've never argued that.

8 MR. LEOPOLD: That is not correct. That is not
9 correct. They have argued that to Judge Saylor and I
10 believe to your Honor. They said, We have been in
11 communications and we've gotten sign-off by the government.
12 That is not -- I'm not aware that that's true. And if that
13 is true, produce the documents. That's what this request
14 is.

15 MS. COBB: I would disagree with Mr. Leopold's
16 characterization of what we've said.

17 Janssen's never requested any sort of OIG advisory
18 opinion on these programs, and we've informed them of that.

19 We obviously don't know what the government internally
20 has done, what their analysis -- if they've done analyses of
21 these programs, and that's what we would like to see from
22 the government. So we don't have the government's obvious
23 internal deliberations or any communications that the
24 government has had on this, and we've never affirmatively
25 sought an OIG advisory opinion on those programs.

1 And I do not believe that we've ever made such a
2 representation to your Honor or to Judge Saylor.

3 THE COURT: Okay. So I think you can just answer
4 RFP 40 to them because it sounds like you have an answer to
5 that, and so we can take care of that one.

6 MR. PRESTON: Your Honor, I think the request
7 goes -- it's broader than that because obviously the
8 decision of whether or not to seek an advisory opinion,
9 right, was a major decision. And maybe they never even
10 considered it, and so then that would be information that
11 they could respond with. But in the event that internally
12 there's discussions of whether we should or should not seek
13 and advisory opinion on whether these services we're
14 providing violate the Anti-Kickback Statute, that's what
15 we're also seeking, the internal deliberations, the internal
16 analysis, not just external communications.

17 THE COURT: So in what world are those kind of
18 analyses not privileged?

19 MR. PRESTON: Your Honor, that's exactly why we
20 need a privilege log. Maybe they decide they don't want to
21 share those documents, but we're entitled to know whether,
22 in fact, they undertook that analysis.

23 MR. POSNER: Yeah, but that's going to require -- I
24 don't even know where I would go to look for something like
25 that. Like, "File on consideration of filing OIG opinions

1 about product support services?" I don't even know where
2 I'd look for that.

3 MR. LEOPOLD: Well, I think, respectfully, all the
4 rules require is a good-faith effort to make inquiries of
5 various departments or groups. That's what's required.

6 And after that review, if it comes back that there
7 isn't any, it's none. But there is a good-faith effort to
8 at least inquire, and that's what the rules are set forth
9 for.

10 So the fact that you may not know where to go, there
11 are people at Janssen that can be talked to to find out that
12 information. That happens all the time.

13 And on the premise that the defendants are arguing that
14 there is no -- there would never be a necessity for a
15 privilege log, because if our position is it should never be
16 produced, why have a privilege log, that's totally contrary
17 to why we have the rules and a privilege log. That just
18 doesn't, respectfully, make sense.

19 I understand why they're making the argument, but it
20 just doesn't hold water.

21 MR. POSNER: But look how far afield we're getting.
22 First they want to know, Did you seek one? Okay. We can
23 answer that. Then they want to know, Did you think about
24 seeking one, and I want you to go do some big search to find
25 out whether you thought about seeking one.

1 MR. PRESTON: I just don't see how it's disputable
2 that whether their internal deliberation as to whether or
3 not they were going to seek an advisory opinion -- it's just
4 not disputable that it's relevant and, in fact, like
5 extremely relevant to the scienter issues in this case.

6 MS. COBB: Your Honor, I think some of this also is
7 dealt with in our appeal now, our motion for reconsideration
8 before you. There are limits to discovery, and the burden
9 that Janssen has already undertaken in this case is
10 significant in terms of the number of documents we've
11 already reviewed and the amount of time and money we have
12 spent. And it seems like at this point we're being asked to
13 uncover every single stone to look for every single whim
14 that relator has, and that is not required under the federal
15 rules.

16 THE COURT: Okay.

17 What else can we cover that is in 235?

18 I see Request 40 there at the end, but I think we just
19 covered that.

20 Let me just ask Janssen, you have produced what you've
21 received from the government?

22 MS. COBB: We have not yet received anything from
23 the government, but we will produce it to relator when we
24 receive any production from the government.

25 THE COURT: And you can do that on a rolling basis?

1 You won't wait until you're sure you have everything from
2 the government. As you receive things, you will turn them
3 over?

4 MS. COBB: Yes.

5 And we produced what we've already produced to the
6 government, but...

7 THE COURT: You mean what you've already received
8 from the government?

9 MS. COBB: Yes.

10 THE COURT: I don't know who was trying to speak.

11 MR. PRESTON: Your Honor?

12 THE COURT: Yes.

13 MR. PRESTON: I just wanted to make the point,
14 right, that pursuant to other document requests, and, in
15 fact, you know, one of the document requests that are at
16 issue in the pending motion, covered within that is
17 Janssen's communications with the Department of Justice
18 concerning this action, not just discovery post declination,
19 but their communications with the government during the
20 government's investigation.

21 And all of that has been withheld. We asked for that a
22 year ago. We've received the actual CID requests. But
23 other than that, all of Janssen's correspondence and
24 communications with the Department of Justice have been
25 withheld.

1 And, in fact, Judge Saylor recently denied Janssen's
2 motion for a protective order where they tried to block us
3 from being able to ask questions about their communications
4 with the Department of Justice during its investigation
5 during the 30(b)(6), and Judge Saylor denied that.

6 So when they say they've produced all the documents
7 regarding communications with the government, that's not
8 true. They have really produced very little of them.

9 THE COURT: Okay.

10 And what's the basis for not producing Janssen's -- I'm
11 addressing Janssen here -- not producing Janssen's
12 communications with the government about the government's
13 investigation?

14 MR. POSNER: Well, your Honor, obviously we've
15 asked that -- I mean, if you want to require both sides to
16 produce the communications back and forth with the
17 government --

18 THE COURT: They say they have with the government
19 and put it on a privilege log in their pleadings here,
20 right?

21 MR. POSNER: Well, yeah, they've logged it as
22 privileged. They haven't produced it, right.

23 THE COURT: Mr. Preston, have you produced any of
24 your communications with the government that are not on a
25 privilege log?

1 MR. PRESTON: Your Honor, I'm glad you've raised
2 this because it shows how they're talking out of both sides
3 of their mouth.

4 All of our communications with the Department of
5 Justice are clearly protected under the work-product
6 privilege and common-interest privilege and, you know, other
7 privileges.

8 We went through a great deal of effort. I'll tell you,
9 we gave to them a much longer privilege log than they gave
10 us. Even those communications are clearly privileged. And,
11 in fact, we went through a lot of effort to redact and give
12 them other communications that didn't contain privileged
13 information.

14 And so it's kind of apples and oranges here. Here
15 they're trying to say they shouldn't have to provide
16 communications that aren't protected by any privilege.
17 These are communications between Janssen and a third party.
18 There's no privilege that applies. And now they're saying
19 they shouldn't have to do that because we asserted a
20 privilege with regard to our protected communications with
21 the Department of Justice.

22 It just seems their -- they clearly have no basis to
23 withhold these communications that they're withholding.

24 MR. POSNER: Your Honor, I'm not sure this is teed
25 up, but obviously our principal objection is one of

1 relevance, right. I mean, our back and forth with DOJ years
2 after the conduct in question is obviously, you know, one
3 significant issue.

4 THE COURT: Okay.

5 Let me just ask, Mr. Preston, can you just -- I think
6 this is in the briefing, but, Mr. Preston, do you want to
7 address the relevancy?

8 MR. PRESTON: First of all, I think Judge Saylor
9 already ruled they're relevant. He denied their protective
10 order.

11 But it's hard to imagine Janssen's communications with
12 as investigative body concerning the relator's claims, how
13 could that not be relevant? I mean, we're entitled to see
14 what Janssen was telling the Department of Justice, you
15 know, what memos, what communications they may have provided
16 as the Department of Justice was investigating these claims.

17 So it's just -- I can't imagine them not being
18 relevant.

19 MR. LEOPOLD: And, your Honor, for purposes of
20 discovery, I cannot imagine it's not relevant. It's a
21 different issue for trial, but for discovery? Clearly it's
22 relevant and can lead to the discovery of admissible
23 evidence. I mean, that's fundamental 101 black law.

24 MR. POSNER: Your Honor, we are prepared to
25 consider the communications with DOJ, but I will want a lot

1 of latitude with respect to the internal DOJ documents and
2 the communications with relator. We're not going to have a
3 one-sided production here. Their view is, Well, tell me
4 what you really told DOJ.

5 It's all going to be helpful to us, obviously.

6 But I will want a lot of latitude on their
7 communications. That is a qualified privilege, and I will
8 want a lot of latitude on internal DOJ stuff because we're
9 not going to do this in my view in a one-sided way.

10 So we are prepared to make a production, which is going
11 to be helpful to us, on our communications with DOJ, but
12 we're going to ask for a lot of latitude on the other side.

13 MR. LEOPOLD: Your Honor, he can ask for whatever
14 he wants.

15 We'll follow the law, and we think we're on very good
16 grounds with the law. He can make whatever motion. We're
17 happy to address it. They have not addressed anything in
18 our privilege log that they've had for well over a month, if
19 not more. Tee it up. We're happy to address it.

20 But, you know, I don't know what -- you know, "We want
21 a lot of latitude." I think what we all want to do is
22 follow the law, whatever the law is, and there is no law
23 that protects them from their privilege that they're
24 arguing. There's none. They have no privilege on that
25 issue.

1 So everything should be produced. And why it has to
2 take, you know, months and month to get a court hearing and
3 we have to argue this when they had no basis to withhold it
4 to begin with, just shows the difficulty we're having in
5 trying to get this case to conclusion. Because every
6 corner, every step, there's a, you know, a stop sign that
7 says, You have to go through us, Janssen, to get to the next
8 level. And, you know, it is what it is. That's the nature
9 of discovery. I get that.

10 But this is not even a well-founded argument. They
11 have no privilege. They should have produced this
12 information.

13 So we would ask for an order, when your Honor writes
14 this order, that within five, ten days all documents are
15 produced. And if Mr. Posner wants some, quote/unquote,
16 latitude, tee up our privilege log, and we're happy to
17 address it with the Court. Whatever the law is, the law is.
18 That's fine.

19 MR. POSNER: Our principal argument was, as we set
20 forth, that sort of production cover letters in 2018 doesn't
21 bear on the legality of the programs in 2016. That's our
22 principal argument, your Honor.

23 THE COURT: Okay. All right. I think I understand
24 the parties' positions. And, yes, I would encourage Janssen
25 to take a look at the privilege log and see what you think

1 of that.

2 Okay. Mr. Preston, or I don't know who else, anything
3 else in 236 you want to raise?

4 MR. LEOPOLD: We stand by our brief.

5 I'm sorry, Casey. I didn't mean to interrupt.

6 MR. PRESTON: It's okay.

7 MR. LEOPOLD: I was going to say we stand by our
8 papers on the rest of it.

9 There is, if I may, your Honor, one other issue.

10 As your Honor may recall, you had ordered that by
11 January 10 the parties submit a status report to your Honor,
12 which we have provided. And that was related to the
13 pre-October Promotional Review Committee materials that
14 we've been told, now for over a month, they're producing,
15 they're looking, they have them, they're now docketing the
16 documents or something, scanning them.

17 We would just like to get a date certain, which they
18 have not been able to provide us, when we're going to get
19 all of the documents. I realize it was the holidays. They
20 had -- somebody had to go to a warehouse. I know they had
21 to scan them, but we're now in the middle of January.

22 You know, is it next week? Is it at the end of January
23 at the latest that we are going to get the documents? I
24 just think we need a date certain.

25 And if, you know, they say -- call us the day before,

1 We need another few days, that's fine. But absent a date
2 certain, it's difficult. We can't have open-ended dates.
3 It's just not fair.

4 And that goes also for the mid 2013 to February 2016
5 PRC materials, documents related to Request 34 and No.4.
6 All of those four things they said they are providing, but
7 they refuse to, respectfully, give us a date when they're
8 going to be due or produced, and I think we're entitled to
9 that.

10 MS. COBB: We have --

11 THE COURT: Okay, yes?

12 MS. COBB: So, yeah. We have -- a few associates
13 went to New Jersey, and we had to review. There were
14 hundreds of boxes that we had to go through, and then all of
15 the documents we found had to be scanned, which, given the
16 holidays, the scanning was finally complete last week. And
17 now they're loaded in the database. But we have to review
18 them before we can produce them. And we told relator's
19 counsel that we would start production on a rolling basis
20 next week, which we are prepared to do. But there are a lot
21 of documents. And so it's not clear that we'll be -- I
22 don't think we can provide an exact date certain when we
23 know we'll be done, but we're aiming to be finish as quickly
24 as possible.

25 THE COURT: Do you have a ballpark on how many

1 documents you're talking about?

2 MS. COBB: Yeah. It's about 15,000 documents that
3 we have to review.

4 THE COURT: And so they need to be reviewed now.

5 MS. COBB: We're in the process of reviewing them
6 now, yes.

7 THE COURT: Okay.

8 Well, why don't we just set a date two weeks from today
9 for your finishing reviewing them. And if at the end of two
10 weeks you're not done, you can tell relator that you're not
11 done and give them a date. I mean, by then you ought to
12 know how many you're able to work through every day.

13 MS. COBB: Yes.

14 THE COURT: And let's produce them on a rolling
15 basis.

16 MS. COBB: Yes.

17 THE COURT: Meaning every other day produce the
18 ones that you're ready to produce.

19 MS. COBB: I'm not sure we can do every other day,
20 just because our vendor takes a couple of days, but if maybe
21 we can agree on two productions a week, that might be
22 doable.

23 THE COURT: Great. All right. So let's give that
24 a shot and see. And does that include everything that
25 Mr. Leopold was just talking about?

1 MS. COBB: Yes.

2 THE COURT: Yes?

3 Okay.

4 MR. LEOPOLD: And, your Honor, just for
5 clarification for our response to the motion for
6 reconsideration, are the issues that we addressed today --
7 essentially is the Court taking under advisement at this
8 point, such as privilege log issues, and where to search,
9 and all those things? Could we reargue them or readdress
10 them, I guess, in the motion for reconsideration? How would
11 the Court like to do this?

12 THE COURT: I'm taking what we argued about today
13 under advisement, and I think you may want to focus on what
14 Janssen objected to. So I think -- I mean, if anyone wants
15 to file something -- anything further after today, like a
16 follow-up memo to any of this that we've been arguing about
17 today, you just must do that, I would say, at the two-week
18 mark, by the 24th. I don't want to see a bunch of filings
19 after that because I just really want to collect everything
20 and get all this to Judge Saylor. He can sort out any
21 objections, and you will have your marching orders in
22 February.

23 MR. LEOPOLD: But absent doing anything further,
24 for example, you will consider, just as an example, the
25 correspondence between Janssen and the government, things of

1 that sort? We don't need -- unless we file something in
2 addition, which I doubt, you're taking that under
3 advisement, and you'll include that in an order, for
4 example?

5 THE COURT: Yes.

6 MR. LEOPOLD: Okay. Thank you.

7 THE COURT: Okay.

8 Also, the sooner you can get in your "sword-and-shield"
9 brief, as we'll call it, the better.

10 And I will just say with regard to the argument on that
11 today, I don't really understand what Janssen is arguing is
12 the import of that committee's work. I don't know what the
13 committee produces, and I don't know what effect it has.
14 And if they're arguing that means they thought it was
15 lawful, that's one thing. I mean -- I would like to focus
16 on this scienter requirement and what type of proof relators
17 hope to have about that.

18 I mean, I don't think you're ever going to get your
19 hands on every privileged document that Janssen has.

20 MR. LEOPOLD: I agree with your Honor, but -- and I
21 wish we had some way to share a document with you, just to
22 give you an understanding of the type of PRC documents that
23 we are provided.

24 But, for example, when the PRC reviews a particular
25 program, they have a document that says "Copy Review

1 Approval Form." And on the form it has various departments
2 that reviewed the PRC program that is at issue. For example,
3 there's Advertising and Promotion, and there's a committee
4 member. And then it has the person's signature that he or
5 she is signing off on. And there's Healthcare Compliance.
6 And there's Legal. And there's Medical Communications. And
7 there's -- basically everybody is signing off on it.

8 On the legal, and just one document, I'm looking at it,
9 a guy -- a gentleman by the name of John Vaughan [ph.] is
10 there. It has his signature, and it has the date that he
11 signed it. That's it. There's no backup information about
12 what John Vaughan did to tell or inform the PRC, or
13 whomever, that this is good to go. It was reviewed, and
14 it's all kosher. This is just a one-page document with his
15 signature.

16 Where's -- what did he do? What analysis did he do?

17 It's -- it is Janssen's position we don't get to ask
18 him that question. We don't get to depose him. We have to
19 take their word for it that there was analysis done, and
20 this one-page sign off by everybody is the Bible, that it's
21 okay.

22 There is nothing on the privilege log indicating that
23 John Vaughan did any analysis, or did any -- so they're
24 saying, okay, we're not relying on advice of counsel, but
25 here's the PRC. There is a lawyer on it. They approved it.

1 So it's okay. We didn't do anything wrong.

2 If we can't depose them and ask them and we can't get
3 behind the curtain and find out what kind of analysis he
4 did, I guess we have to rely on the truthfulness, with all
5 due respect, of Janssen to say, Oh, yeah, John Vaughan did
6 this whole analysis, this whole dissertation, on why this
7 program was okay. See, there's this one-page thing. He
8 just has his signature on it and the date that he signed it.
9 And it says, you know, it's okay. It's okay. Everybody
10 signed off on it. It's okay to use it.

11 That's where we're at, and that -- again, we'll brief
12 this. But there are a number of Federal Circuit Court cases
13 on this particular issue. You can't do that.

14 And if they do rely on that, we are entitled to inquire
15 about the backup.

16 MR. POSNER: Yeah, I mean, look. He's
17 mischaracterized our position. We will respond and answer
18 your Honor's question about the PRC when they file this
19 brief they haven't filed yet.

20 THE COURT: Okay.

21 All right. So I think that's all for today. Anyone
22 else want to raise anything else?

23 MR. PRESTON: Your Honor, if I just may, just to
24 have a -- there have been different dates that have been
25 sort of mentioned, and I just want to make sure we're clear

1 on sort of the schedule and we now have sort of two
2 important briefs that are going to be worked on at the same
3 time.

4 Would it be permissible to have a due date for both
5 briefs of January 28?

6 THE COURT: Okay. So I have previously said that
7 your opposition to Janssen's motion, which I'm calling it a
8 motion to reconsider but it was an appeal of my order, was
9 due on the 26th. But now you want to file that on the 28th,
10 plus --

11 MR. PRESTON: Well, I think there may be overlap,
12 and to the extent that there's a uniform date, it may be
13 helpful.

14 THE COURT: Okay. You can have until the 28th for
15 the opposition to the motion that Janssen filed with
16 Judge Saylor, and then you're also going to file a motion
17 concerning waiver, I think, right?

18 MR. PRESTON: Yes, your Honor.

19 Thank you.

20 THE COURT: All right. And then Janssen will want
21 to respond to that, correct?

22 MR. POSNER: Yup.

23 THE COURT: Okay. And when do think you might want
24 to respond to that?

25 MR. POSNER: Well, I mean, their original response

1 to our appeal, if it was going before the District Court,
2 would have been due the 24th, but they're getting four more
3 days. I mean, obviously we're going to want -- you know,
4 it's hard for -- we're going to want two weeks to respond to
5 this brief they haven't filed yet. But I'm sure we may
6 want a short -- we'll combine it, but there may be some
7 things we'll quickly say in reply on the reconsideration.
8 But I guess two weeks, your Honor.

9 THE COURT: So why don't we say you'll file
10 whatever you want to file on the 11th, okay?

11 MR. POSNER: Okay. Thank's, your Honor.

12 THE COURT: All right. And, Mr. Preston, any other
13 dates you wanted to go over?

14 MR. PRESTON: Your Honor, I think those are the
15 dates at issue right now. I appreciate the clarification on
16 that.

17 THE COURT: Okay.

18 All right. So anything else, anyone?

19 MR. LEOPOLD: Thank you for your time, your Honor.
20 We appreciate it very much.

21 MR. POSNER: Thank you, your Honor.

22 THE COURT: Well, thank you. Thank you very much.

23 MR. PRESTON: Thank you.

24 MR. POSNER: Stay well, everyone. Thanks.

25 (Proceedings adjourned.)

C E R T I F I C A T E

I, James P. Gibbons, Official Court Reporter for the United States District Court for the District of Massachusetts, do hereby certify that the foregoing pages are a true and accurate transcription of my shorthand notes taken in the aforementioned matter to the best of my skill and ability.

/s/James P. Gibbons
James P. Gibbons

February 11, 2022

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